

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

CHEZAREE BOOKER and QWONJIT
NELSON, individually and on behalf of all
others similarly situated,

Case No. 7:20-cv-03166 (PMH)

Plaintiffs,

v.

E.T. BROWNE DRUG CO., INC.,

Defendant.

**DEFENDANT E.T. BROWNE DRUG CO., INC.’S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFFS’
CLASS ACTION COMPLAINT**

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PRELIMINARY STATEMENT

Defendant E.T. Browne Drug Co., Inc. (“Defendant” or “E.T. Browne”) manufactures, advertises, and distributes cosmetic products, including Palmer’s Massage Lotion for Stretch Marks, Massage Cream for Stretch Marks, and Tummy Butter for Stretch Marks (collectively, the “Products”). The Products are marketed for application on the skin to “help[] reduce the *appearance* of stretch marks”—a claim consistent with the Federal Food, Drugs, and Cosmetic Act’s (“FDCA”) express definition of a cosmetic: articles that are applied on the body for, *inter alia*, altering the *appearance*. The Products’ labeling and packaging show that they do this by “moisturizing” the skin, which the Food and Drug Administration (“FDA”), the federal agency responsible for enforcing the FDCA, has recognized as a permissible cosmetic claim.

Plaintiffs allege that E.T. Browne falsely advertises its Products. Plaintiffs do so by misrepresenting a series of studies and articles, of which the Court can take judicial notice, which do not purport to test the cosmetic claim made by the Products, *i.e.*, that they help reduce the appearance of stretch marks. Instead, the studies and articles concern whether cocoa butter preparations generally deliver certain drug effects namely, preventing or treating stretch marks.

As a result, Plaintiffs’ claims fail for two separate but related reasons. *First*, Plaintiffs’ claims are preempted by the FDCA because they seek to hold E.T. Browne’s cosmetic Products to the standards applicable to drug claims, which differ from the FDCA requirements for cosmetic claims. Plaintiffs’ claims rely on studies purportedly showing that the Products do not produce a *physiological* result, *e.g.*, that they do not treat or prevent stretch marks, and therefore seek to make E.T. Browne have scientific support for drug claims that the cosmetic Products do not make. Their attempt to impose that requirement under state law vitiates the FDCA’s distinction between cosmetic claims and drug claims because it is not identical to the requirements of the FDCA. *Second*, the stark disconnect between Plaintiffs’ studies and the

cosmetic Products' advertising is fatal to Plaintiffs' complaint. None of Plaintiffs' cited studies support what Plaintiffs allege in their Complaint. The studies do not conclude that the Products cannot help reduce the appearance, or look, of stretch marks; instead they conclude that cocoa butter preparations may not be effective in the clinical treatment and prevention of stretch marks. In other words, the studies concern a claim that the Products do not make. Indeed, one of Plaintiffs' own studies recognizes that moisturizers such as the Products "can improve the appearance of stretch marks." This alone is grounds to dismiss the Complaint in its entirety.

Accordingly, all of Plaintiffs' claims—which contend that the Products do not perform as labeled—fail. Further, Plaintiffs' unjust enrichment claim warrants dismissal because it is duplicative of their other claims and does not allege that Plaintiffs' lack an adequate remedy at law as required to plead unjust enrichment.

For all of these reasons, which are detailed below, the Court should dismiss Plaintiffs' Complaint against E.T. Browne in its entirety, with prejudice.

STATEMENT OF ALLEGED FACTS

I. E.T. Browne's Palmer's Products are Cosmetics Marketed to Help Reduce the Appearance of Stretch Marks

Defendant E.T. Browne manufactures and distributes "cosmetic products," including Palmer's Massage Lotion for Stretch Marks, Massage Cream for Stretch Marks, and Tummy Butter for Stretch Marks. *See* Compl. ¶¶ 1, 15, 48, 55. The Products are labeled and marketed to "help[] reduce the appearance of stretch marks." *Id.* ¶ 2.



Id. at 2; *see also* RJD, Exs. A–C.¹ The back of the Massage Cream box and tube packaging states that “Palmer’s® Massage Cream helps visibly improve skin elasticity and reduce the appearance of stretch marks. Pure Cocoa Butter and Shea Butter, Natural Oils, Collagen, Elastin and Lutein keep skin moisturized and supple for 48 hours”. RJD, Ex. A. The back of the Massage Lotion packaging contains similar claims. *See id.* Ex. B.

¹ The complete labels for the Products are attached to E.T. Browne’s Request for Judicial Notice (“RJD”), filed concurrently herewith. RJD, Exs. A–C.

Plaintiff Chezaree Booker is a citizen of New York and allegedly purchased a bottle of Palmer's Cocoa Butter Formula Massage Lotion for Stretch Marks from CVS in January 2020 for approximately \$8. Compl. ¶ 13. She purports to have previously purchased other Products, including the Tummy Butter in 2019. *See id.* Plaintiff Qwonjit Nelson is also a citizen of New York and allegedly purchased a tub of Palmer's Cocoa Butter Formula Tummy Butter for Stretch Marks from Walgreens in December 2019 for approximately \$7. *Id.* ¶ 14. She purports to have previously purchased the Massage Lotion in 2019. *Id.*

Plaintiffs allegedly relied on the Products' representations that they are "for stretch marks" and "help[] reduce the appearance of stretch marks" in making their purchases. *Id.* ¶¶ 13, 14. Both allege to have "used the Products as directed but they did not prevent or reduce the appearance of stretch marks as advertised." *Id.* Plaintiffs claim that they "would not have purchased the Products at all, or would have only been willing to pay a substantially reduced price" for the Products, had they known the Products' claims were "false and misleading." *Id.*

Plaintiffs purport to represent a class comprising all individuals in the United States who purchased the Products. *Id.* ¶ 19. Plaintiffs further purport to represent a subclass of all individuals who purchased the Products in New York. *Id.* ¶ 20.

II. Plaintiffs' Studies Focus Entirely on Drug Claims that the Products Do Not Make—the Prevention and Treatment of Stretch Marks

To support their allegations that the Products' claims are "false and misleading," Plaintiffs mischaracterize a series of studies and articles which do not address whether the Palmer's Products "help[] reduce the appearance of stretch marks." Plaintiffs' studies and

articles, of which this Court may take judicial notice,² instead focus entirely on the prevention, development, and treatment of stretch marks.

Ud-Din Article (RJN, Ex. D): Plaintiffs rely upon a 2016 article that, by their own allegations, considered “the efficacy of different *treatments for the prevention* of stretch marks.” Compl. ¶ 4 (emphases added) (citing S. Ud-Din et al., *Topical Management of Striae Distensae (Stretch Marks): Prevention and Therapy of Striae Rubrae and Albae*, 30 J. of the Eur. Acad. of Dermatology and Venereology 211 (2016) (“Ud-Din Article”)). The Ud-Din Article did not itself study any products, but instead reviewed published literature and manufacturer website information on the use of topicals in the *treatment and prevention* of various stages of *striae distensae* (stretch marks). *See* Ud-Din Article at 211. The Article reviewed “two randomized controlled trials, which have investigated the effects of cocoa butter vs. a placebo, *for the prophylactic [i.e., preventive] treatment* of [stretch marks].” *Id.* at 219 (emphasis added). The Ud-Din Article concluded that “there is a need for a structure to identify which topical treatments can address the patient’s signs and symptoms and type of [stretch marks]” and that “[f]urther high-quality randomized controlled trials are necessary to assess the efficacy of topical products for the *prevention and treatment* of [stretch marks].” *Id.* at 221 (emphasis added).

Osman Study (RJN, Ex. E): Plaintiffs cite to a 2008 study that “assess[ed] whether application of cocoa butter lotion reduces the *development of*” stretch marks. *See* H. Osman et al., *Cocoa Butter Lotion for Prevention of Striae Gravidarum: A Double-Blind, Randomised and Placebo-Controlled Trial*, 115 BJOG 1138, 1138 (2008) (“Osman Study”) (emphasis added); *see*

² Plaintiffs’ studies and articles are attached to E.T. Browne’s RJN, filed concurrently herewith. RJN, Exs. D–I.

also Compl. ¶ 5 (citing Osman Study).³ The Osman Study focused entirely on whether cocoa butter prevents stretch marks and whether it can effectively treat stretch marks. *See e.g.*, Osman Study at 1142 (emphases added) (“our analysis was based on *intent to treat*”). The Osman Study concluded that its “findings do not support the use of cocoa butter lotion for the *prevention* of [stretch marks]. Further studies are needed to confirm our findings in other populations and to evaluate the effectiveness of other commonly used products in *preventing* [stretch marks].” *Id.* (emphases added).

Buchanan Study (RJN, Ex. F): Plaintiffs rely upon a study with an objective of “determin[ing] whether cocoa butter cream is effective in *preventing*” stretch marks. *See* Keisha Buchanan et al., *Prevention of Striae Gravidarum with Cocoa Butter Cream*, 108 Int’l J. of Gynecology and Obstetrics 65, 65 (2009) (“Buchanan Study”) (emphasis added); *see also* Compl. ¶ 6 (citing Buchanan Study).⁴ The Buchanan Study enrolled 300 pregnant women in a placebo-controlled trial and provided 150 women with cocoa butter cream and the other 150 with a placebo cream. *See* Buchanan Study at 65. “The women were followed-up from 16 weeks of pregnancy to delivery to assess the *development of*” stretch marks. *Id.* (emphasis added). The Buchanan Study ultimately concluded that “[c]ocoa butter cream does not *prevent*” stretch marks. *Id.* (emphasis added).

Brennan Review (RJN, Ex. G): Plaintiffs rely on a review that “assess[ed] the effects of topical preparations on the *prevention* of stretch marks in pregnancy.” *See* M. Brennan et al.,

³ Although the Complaint alleges that the “study tested the efficacy of the Products” (Compl. ¶ 5), the Osman Study actually states that “E.T. Browne Drug Company, Inc. provided the study and placebo lotions,” but does not state that it tested any of the Products at issue. Osman Study at 1142 (RJN, Ex. E).

⁴ The Complaint falsely alleges that “[t]he Products also flunked” (Compl. ¶ 6) the Buchanan Study because the Buchanan Study makes no mention whatsoever of E.T. Browne, Palmer’s, or any of the Products. *See* Buchanan Study (RJN, Ex. F).

Topical Preparations for Preventing Stretch Marks in Pregnancy, 11 Cochrane Database of Systematic Reviews 1, 1 (2012) (“Brennan Review”) (emphasis added); *see also* Compl. ¶¶ 8, 9. The Brennan Review analyzed trials comparing topical preparations containing active ingredients with placebos or “no *treatment*” “for the *prevention* of stretch marks in pregnant women.” Brennan Review at 1 (emphases added). By Plaintiffs’ own allegations, the Brennan Review concluded that “there was no statistically significant average difference in the *development of stretch marks* in women who received topical preparations with active ingredients compared to women who received a placebo or no *treatment*.” Compl. ¶ 8 (citing Brennan Review at 1).

Hague Review (RJN, Ex. H): Plaintiffs cite another review, which “evaluate[d] and summarize[d] the different *treatment methods* for [stretch marks] by linking their proposed modes of action with the histopathogenesis⁵ of the condition to guide *patient treatment*.” Hague, Adam et al., *Therapeutic targets in the management of striae distensae: A systematic review*, 77 J. of the Amer. Acad. of Dermatology, 559 (2017) (“Hague Review”) (emphases added); *see also* Compl. ¶ 9. As the Ud-Din Article and Brennan Review, the Hague Review did not itself study any products; it instead relied upon published literature, including the Osman and Buchanan Studies. *See* Hague Review at 559, 564, 565, 568.e17. And, as discussed above, the Hague Review states that the Osman and Buchanan studies both compared cocoa butter with a placebo and found “[n]o significant differences in the *development of new [stretch marks]*.” *See id.* at 568.e17 (emphases added) (citing the Osman and Buchanan Studies).

⁵ “Histopathogenes”: “the origin and development of diseased tissue.” *Merriam-Webster.com Medical Dictionary*, Merriam-Webster, available at <https://www.merriam-webster.com/medical/histopathogenesis> (accessed Sept. 17, 2020).

Moore Article (RJN, Ex. I): Finally, Plaintiffs rely on an article published in the Journal of Family of Medicine that similarly discusses the Osman and Buchanan Studies. *See* Moore, J. et al., *Do any topical agents prevent or reduce stretch marks?*, 61 J. of Family Practice 757 (2012) (“Moore Article”); *see also* Compl. ¶ 9. The Moore Article states that the Osman and Buchanan Studies’ randomized controlled trials demonstrate that “cocoa butter doesn’t prevent stretch marks.” Moore Article at 757 (emphasis added). By Plaintiffs’ own allegations, the Moore Article concludes that “although many creams, lotions, and oils on the market *claim to prevent stretch marks, no proof exists that these treatments work.*” Compl. ¶ 9 (emphases added) (citing Moore Article at 758). Critically, the subsequent paragraph of the Moore Article acknowledges that “[t]he American Academy of Dermatology Web site also says that *a moisturizer can improve the appearance of stretch marks* and reduce itchiness” Moore Article at 758 (emphases added). The Moore Article’s acknowledgment that “moisturizer[s] can improve the appearance of stretch marks” is thus consistent with the Products’ claim that they “help[] reduce the appearance of stretch marks.”

III. Plaintiffs’ Claims Against E.T. Browne Rely on Allegations That the Products’ Representations Are False, Deceptive, or Misleading

Plaintiffs allege five causes of action for: (1) deceptive acts or practices under New York General Business Law Section 349 (Count I) (Compl. ¶¶ 26–32); (2) false advertising under New York General Business Law Section 350 (Count II) (*id.* ¶¶ 33–39); (3) unjust enrichment (Count III) (*id.* ¶¶ 40–45); (4) breach of express warranty (Count IV) (*id.* ¶¶ 46–51); and (5) fraud (Count V) (*id.* ¶¶ 52–57). Plaintiffs seek compensatory, statutory, and punitive damages, and restitution.⁶

⁶ Pursuant to Your Honor’s Rule I.4.C.ii, E.T. Browne sent Plaintiffs a letter on June 8, 2020, setting forth the grounds to dismiss the Complaint. On June 15, 2020, Plaintiffs sent their letter

STANDARD OF REVIEW

A court may dismiss a complaint for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss, Plaintiffs “must allege enough facts to state a claim to relief that is plausible on its face,” and “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Tomasino v. Estee Lauder Companies Inc.*, 44 F. Supp. 3d 251, 256–57 (E.D.N.Y. 2014) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A claim is plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678.

On a motion to dismiss, “the court may consider documents that are referenced in the complaint, documents that plaintiffs relied on in bringing suit (that are either in the plaintiffs’ possession or were known to plaintiffs at the time they brought suit), or matters of which judicial notice may be taken.” *Levy v. Verizon Info. Servs., Inc.*, 498 F. Supp. 2d 586, 593 (E.D.N.Y. 2007) (citing *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002)). Plaintiffs include part of the Palmer’s Products’ labels in their Complaint. *See* Compl. at 2. The Court can take judicial notice of the Products’ complete labels, which show that the Products have extensive and unique lists of ingredients beyond the “active ingredients” Plaintiffs plead. *See, e.g., Bowring v. Sapporo U.S.A., Inc.*, 234 F. Supp. 3d 386, 389 (E.D.N.Y. 2017) (taking judicial notice of “complete labels for each variety of [] beer” challenged by plaintiff); *see also* Fed. R. Evid. 201(b) (“[t]he court may judicially notice a fact that is not subject to reasonable dispute”).

response disputing E.T. Browne’s grounds for dismissal, but agreeing to drop their request for injunctive relief.

The Court can also take judicial notice of the studies and articles cited by Plaintiffs as documents incorporated by reference into the Complaint. *See Kalyanaram v. Am. Ass'n of Univ. Professors at New York Inst. of Tech., Inc.*, 742 F.3d 42, 44 n.1 (2d Cir. 2014) (“[A] court may consider the complaint as well as any written instrument attached to the complaint as an exhibit or any statements or documents incorporated in it by reference.”) (citation omitted). And, “[w]hile the Court must accept the allegations in the complaint as true, to the extent any allegations directly contradict evidence contained in the documents relied upon by a plaintiff, the documents control, and the allegations need not be accepted as true.” *Sobek v. Quattrochi*, No. 03 CIV.10219, 2004 WL 2809989, at *2 (S.D.N.Y. Dec. 8, 2004).

ARGUMENT

- I. PLAINTIFFS’ STATE LAW CLAIMS ARE ALL PREEMPTED BY THE FDCA BECAUSE THEY SEEK TO IMPOSE REQUIREMENTS FOR DRUG CLAIMS, WHICH DIFFER FROM THE FDCA’S STANDARDS FOR COSMETIC CLAIMS**
 - A. The Products Are “Cosmetics” Under the FDCA and Their Cosmetic Labeling Is Proper Under the FDCA**

The FDCA was enacted “as part of a comprehensive federal regulatory scheme to protect consumers from fraud or misrepresentation in the sale of food, drugs, and cosmetics.” *O’Connor v. Henkel Corp.*, No. 14-CV-5547, 2015 WL 5922183, at *3 (E.D.N.Y. Sept. 22, 2015). The FDA, the federal agency in charge of enforcing the FDCA, “protect[s] public health by ensuring, *inter alia*, that ‘drugs are safe and effective,’ and that ‘cosmetics are safe and properly labeled.’” *Id.* (citing 21 U.S.C. § 393(b)(2)(B) & (D)).

The FDCA expressly defines a “cosmetic” as an article “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or *altering the appearance.*” 21 U.S.C. § 321(i) (emphases added). FDA guidance similarly explains that cosmetics are products

“intended to be applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance” and “intended to exert a physical, and not a physiological, effect on the human body.” *Cosmetics Labeling Guide*, U.S. FOOD & DRUG ADMINISTRATION (current as of Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide> (“FDA: Cosmetics Labeling Guide”). In contrast, a product is a drug “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or in the case of non-food products, “to affect the structure or any function of the body.” 21 U.S.C. § 321(g)(1)(B) & (C).

The FDA has expressly stated that “moisturizing is a cosmetic claim.” *Wrinkle Treatments and Other Anti-aging Products*, U.S. FOOD & DRUG ADMINISTRATION (current as of Sept. 11, 2020), <https://www.fda.gov/cosmetics/cosmetic-products/wrinkle-treatments-and-other-anti-aging-products> (“FDA: Wrinkle Treatments”). Therefore, “[i]f cosmetic claims, e.g., moisturizing, deodorizing, skin softening etc., are made on a label, the product is a cosmetic.” FDA: Cosmetics Labeling Guide. For example, “if a product is intended to make lines and wrinkles less noticeable, simply by moisturizing the skin, it’s a cosmetic. Similarly, makeup or ‘primers’ intended to make the signs of aging less noticeable just by hiding them are also cosmetics.” FDA: Wrinkle Treatments. This is also consistent with the Moore Article cited by Plaintiffs, which recognizes that “moisturizer[s] can improve the appearance of stretch marks.” Moore Article at 758 (RJN, Ex. I).

Under the FDCA and FDA guidance, the Products are cosmetics because: (1) they are skin moisturizers and (2) they claim to affect the *appearance of* stretch marks by moisturizing the skin. *First*, the products at issue—skin moisturizers such as lotions, creams, and body butters (*see* Compl. ¶ 1)—are considered “cosmetics.” *See* 21 C.F.R. § 720.4(c)(12) (cosmetics include

“[s]kin care preparations, (creams, lotions, powder, and sprays)”). *Second*, the Products do not claim to prevent or treat stretch marks or affect the structure or function of the body; instead, they claim to affect *the appearance of* stretch marks, which the FDA recognizes as a cosmetic claim. As noted above, the Court can take judicial notice of the Products’ labels, which demonstrate that they are moisturizers and affect the appearance of stretch marks by moisturizing the skin. *See, e.g., Bowring*, 234 F. Supp. 3d at 389 (taking judicial notice of product labels). For example, on the back labels of the Massage Lotion and Massage Cream, and in close proximity to the claim that they “help[] visibly improve skin elasticity and reduce the appearance of stretch marks,” the products state that they “keep skin *moisturized* and supple for 48 hours.” RJN, Exs. A, B (emphasis added). The FDCA and FDA guidance make clear that the Products at issue are indeed cosmetics, not drugs.

B. The FDA Has Expressly Addressed the Subject Matter of Plaintiffs’ Claims

The FDCA expressly preempts state law claims imposing requirements or obligations for cosmetic labeling that are different from the FDCA or FDA regulations: “any state law establishing or continuing any requirement for labeling or packaging ‘that is different from or in addition to, or that is otherwise not identical with’ a requirement of the FDCA or enumerated federal statutes.” *O’Connor*, 2015 WL 5922183, at *3 (citing 21 U.S.C. § 379s). “[P]laintiffs can escape the preemptive force of the FDCA only if their claims seek to impose requirements that (1) are identical to those imposed by the FDCA, or (2) are outside the scope of the relevant federal requirements.” *Id.* at *5. In determining whether Plaintiffs’ claims are preempted, the proper inquiry is whether Congress and/or the FDA has addressed the subject matter of their claims. *See Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749, 2015 WL 5256988, at *4, 6 (S.D.N.Y. Sept. 9, 2015).

Here, Congress and the FDA have addressed the subject matter of Plaintiffs' claims by expressly providing a definition for "cosmetics," which includes products that alter the appearance of the body. *See supra* Argument I.A.; *see Jovel v. i-Health, Inc.*, No. 12-CV-5614, 2013 WL 5437065, at *5 (E.D.N.Y. Sept. 27, 2013) (emphases added) (holding that claims were not preempted because they "do not require reference to FDA definitions and the misleading nature of the statement can be verified without relying on any special expertise of the FDA"). And, the FDA has said that "moisturizing is a cosmetic claim" and that "if a product is intended to make lines and wrinkles less noticeable, simply by moisturizing the skin, it's a cosmetic." FDA: Wrinkle Treatments; *see also* FDA: Cosmetics Labeling Guide ("If cosmetic claims, e.g., moisturizing, deodorizing, skin softening etc., are made on a label, the product is a cosmetic.").

Finally, the FDA has shown that it is willing and able to act when it determines that advertising claims related to stretch marks constitute a drug claim rather than a cosmetic claim. For example, the FDA issued a warning letter upon reviewing claims on a website "establish[ing] that the products are drugs" under the FDCA because the "new drugs" had not received prior approval from FDA. *Long Life Unlimited Warning Letter*, U.S. FOOD & DRUG ADMINISTRATION (Jan. 31, 2018), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/long-life-unlimited-533282-01312018> ("FDA: Warning Letter). One of the products at issue claimed to be a "a soothing salve for *treatment* of the symptoms resulting from" "Stretch Marks (also aids in *prevention*)." *Id.* (emphases added). This FDA guidance further demonstrates that Plaintiffs' claims should be found preempted.

C. Plaintiffs' Attempt to Impose a Drug Standard On E.T. Browne's Cosmetic Claims Is Preempted By the FDCA

The Products are labeled and marketed to "help[] reduce the appearance of stretch marks." *See* RJD, Exs. A–C. The Products do not claim to produce a *physiological* result on the

body—that is, the Products do not claim to affect stretch marks by treating or preventing their development. Rather, the cosmetic Products claim to affect the *appearance*, or look, of stretch marks. Notwithstanding this critical difference, the entire Complaint relies on studies purporting to show that the Products do not produce a *physiological* result on the body to support their claims that the Products’ cosmetic marketing is false and misleading. *See e.g.*, Compl. ¶ 4 (emphases added) (citing the Ud-Din Article which considered “the efficacy of different *treatments for the prevention* of stretch marks”); *id.* ¶ 5 (emphasis added) (relying on the Osman Study, which concluded that its “findings do not support the use of cocoa butter lotion for the *prevention of* stretch marks); *id.* ¶ 6 (emphasis added) (citing the Buchanan Study which “determine[d] whether cocoa butter cream is effective in *preventing*” stretch marks); *id.* ¶ 8 (emphases added) (relying on the Brennan Review, which found that “[t]here was no statistically significant average difference in the *development of stretch marks* in women who received topical preparations with active ingredients” versus a placebo or “no *treatment*”); *id.* ¶ 9 (emphases added) (relying on the Hague Review, which “evaluate[d] and summarize[d] the different *treatment methods for*” stretch marks); *id.* (relying on the Moore Article, which addressed the prevention and treatment of stretch marks while distinctly recognizing that moisturizers can improve their appearance). In other words, Plaintiffs seek to make E.T. Browne produce scientific support for drug claims that the Products do not make, and that is preempted by the FDCA.

In *Dachauer v. NBTY, Inc.*, 913 F.3d 844 (9th Cir. 2019), the plaintiff similarly claimed that the defendants’ vitamin E supplements falsely advertised they “support cardiovascular health,” “promote immune function,” “immune health,” “heart health,” and “circulatory health” because they did not prevent cardiovascular disease. *Id.* at 846. The Ninth Circuit held that

plaintiff's claims were preempted by the FDCA. *Id.* at 848. It pointed out that the FDCA distinguishes between "disease claims" and "structure/function"⁷ claims. *Id.* at 846. The Court explained:

Defendants' labels *do not claim* that their vitamin E *supplements treat or prevent cardiovascular disease*. Yet Plaintiff seeks to impose a requirement under California law that structure/function claims—at least those related to cardiovascular, circulatory, and heart health—made on a supplement's label require proof that the supplement treats or prevents cardiovascular disease. That requirement "is not identical to the requirement of section 343(r)."

Id. at 848 (emphases added) (citing 21 U.S.C. § 343-1(a)(5)). The Court rejected plaintiff's argument that "it does not matter whether he categorizes Defendants' claims as structure/function claims or as disease claims, because he addressed the falsity of the labels' text" because that argument "would vitiate the FDCA's distinction between disease claims and structure/function claims." *Id.*

Similarly, Plaintiffs seek to impose on E.T. Browne a requirement that is applied to new drugs that must be submitted to the FDA, not to cosmetics. *See* 21 U.S.C. 321(p)(1) ("Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . ."); *see also Brinkerhoff v. L'Oreal USA, Inc.*, 417 F. Supp. 3d 1308, 1312

⁷ Unlike cosmetics, which may not claim to alter the structure or function of the body, dietary supplements, a food, may make "structure/function" claims—that is, claims "describ[ing] the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body"—which are distinct from drug claims. *Structure/Function Claims*, U.S. FOOD & DRUG ADMINISTRATION (current as of Dec. 14, 2017), <https://www.fda.gov/food/food-labeling-nutrition/structurefunction-claims>; *see* 21 U.S.C. § 321(g)(1). Nevertheless, *Dachauer's* reasoning is equally applicable to the FDCA's distinction between drug claims and cosmetic claims. Any attempt by Plaintiffs to impose a drug standard on a non-drug product, whether a supplement or a cosmetic, is preempted.

(S.D. Cal. 2019) (“unlike purely cosmetic items, ‘new drugs’ generally may not be marketed or sold without preapproval from the FDA”); *Dachauer*, 913 F.3d at 848 (“Manufacturers need not also have evidence that those structural or functional effects reduce the risk of developing a certain disease.”). Plaintiffs’ requirements are thus not identical to the requirements of 21 U.S.C. § 321(i) and “vitiate the FDCA’s distinction between” cosmetic claims and drug claims. *Dachauer*, 913 F.3d at 848. Therefore, Plaintiffs’ claims are preempted. *Id.* (holding that plaintiff’s claims were preempted by the FDCA “to the extent that he argues that Defendants’ [advertising is] false or misleading because their supplements do not prevent cardiovascular disease”).⁸

II. ALTERNATIVELY, PLAINTIFFS FAIL TO STATE A CLAIM THAT THE PRODUCTS’ REPRESENTATIONS ARE FALSE, DECEPTIVE, OR MISLEADING BECAUSE THEIR STUDIES CONCERN DRUG CLAIMS THAT THE PRODUCTS DO NOT MAKE

Plaintiffs’ claims should be dismissed because none of Plaintiffs’ studies show that the Products cannot “help[] reduce the appearance of stretch marks.” Plaintiffs’ claims require a showing that E.T. Browne engaged in misrepresentation in advertising its Products—(i) New York General Business Law Sections 349 and 350 require a showing that the advertising was false and misleading (*see* N.Y. Gen. Bus. Law §§ 349, 350); (ii) breach of the express warranty requires a showing that the Products did not conform with an express warranty (*see* *Tomasino*, 44 F. Supp. 3d at 263); and (iii) fraud requires that plaintiffs allege a material misrepresentation which E.T. Browne knew to be false (*Bowring*, 234 F. Supp. 3d at 392).

⁸ To the extent Plaintiffs would purport to enforce the FDCA, such private enforcement is prohibited under New York law. *See Verzani v. Costco Wholesale Corp.*, No. 09 CIV 2117, 2010 WL 3911499, at *3 (S.D.N.Y. Sept. 28, 2010), *aff’d*, 432 F. App’x 29 (2d Cir. 2011) (“The FDCA lacks a private right of action and therefore [plaintiff] cannot rely on it for purposes of asserting a state-law consumer claim under G.B.L. § 349.”); *see also O’Connor*, 2015 WL 5922183, at *3. Plaintiffs’ state law claims premised on any purported violations of the FDCA therefore cannot survive this motion to dismiss.

The entire Complaint relies on a theory of misrepresentation based upon studies that Plaintiffs falsely claim show that “the Products do not prevent or reduce the appearance of stretch marks.” Compl. ¶ 3. The Court is entitled to read the studies Plaintiffs cite in the Complaint. And, “where scientific studies are cited and thus incorporated into the complaint, and where those studies simply do not support the allegations, the Court may find that the deficiencies . . . go to the very heart of the plausibility standard under *Iqbal*.” *Sabol v. Bayer Healthcare Pharm., Inc.*, 439 F. Supp. 3d 131, 148 (S.D.N.Y. 2020) (citation omitted); *see also Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 140–41 (E.D.N.Y. 2015) (analyzing plaintiffs’ studies to assess claims on a motion to dismiss because “where a conclusory allegation in the complaint is contradicted by a document attached to the complaint, the document controls and the allegation is not accepted as true”) (quoting *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 146–47 (2d Cir. 2011)).

None of Plaintiffs’ studies undercuts the Products’ claims that they help reduce the appearance, or look, of stretch marks because the studies instead focus entirely on drug claims that the Products do not make: the prevention and/or treatment of stretch marks. Further, one of Plaintiffs’ studies directly contradicts Plaintiffs’ claims by acknowledging that moisturizers can indeed improve the appearance of stretch marks.

A. The “Stark Disconnect” Between Plaintiffs’ Studies and the Products’ Labeling Requires Dismissal of the Complaint

In *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131 (E.D.N.Y. 2015), plaintiffs brought a putative class action against a pharmaceutical company for alleged deceptive labeling of vitamins. Plaintiffs relied on scientific materials that addressed different health issues than those addressed by defendant’s underlying representations. *Id.* at 137–38. The Court found that “[b]ecause of these ‘mismatches,’ . . . the science does not undercut [the product’s] statements

regarding its health benefits, and thus, plaintiffs have failed to raise a plausible claim that [the product's] representations are false, deceptive, or misleading under the standards set out in the various state laws invoked here.” *Id.* at 138.

Here, the studies and other literature that Plaintiffs rely upon concern the prevention and treatment of stretch marks. Because each of Plaintiffs’ studies focuses on *drug* claims, and not the Products’ *cosmetic* claim, there is a “stark disconnect” between Plaintiffs’ studies and the Products’ claim that requires dismissal of the Complaint. *Id.*; *see id.* (“[W]here plaintiffs point to scientific studies that they allege actually disprove a product’s claims, such a stark disconnect between the scientific studies and the claims made about [the product’s] benefits is fatal to plaintiffs’ complaint.”); *Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727, 2012 WL 5382218, at *7 (S.D. Cal. Nov. 1, 2012) (dismissing the complaint because “the Court [could not] accept that the studies [plaintiff] cites lend ‘facial plausibility’ to her claims that the [product] representations are false or misleading”).

B. None of Plaintiffs’ Studies Assess Whether the Palmer’s Products Reduce the Appearance of Stretch Marks

Plaintiffs first cite the Ud-Din Article. *See* Compl. ¶ 4. The Article reviewed published literature and manufacturer website information for topicals on the treatment and prevention of various stages of *striae distensae* (stretch marks). *See* Ud-Din Article at 211 (RJN, Ex. D). By Plaintiffs’ own allegations, the Ud-Din Article considered “the efficacy of *different treatments for the prevention* of stretch marks.” Compl. ¶ 4 (emphases added) (citing Ud-Din Article). The Article itself did not test any topicals. Instead, the Article summarized various studies, including the Osman and Buchanan Studies (discussed herein) which assessed the prophylactic treatment of stretch marks. *See* Ud-Din Article at 215 (RJN, Ex. D) (“type of treatment”: “prophylactic”).

The Ud-Din Article did not assess whether the Palmer's Products reduce the appearance of stretch marks.

Next, Plaintiffs cite the Osman Study, which “assess[ed] whether application of cocoa butter lotion *reduces the development of* stretch marks. Osman Study at 1138 (RJN, Ex. E) (emphases added). The Study analyzed the prophylactic treatment of cocoa butter on the development of stretch marks and compared that treatment with application of a placebo. *See id.* at 1139. Plaintiffs disingenuously claim that the Products “flunked” the Osman Study testing (*see* Compl. ¶ 5),⁹ because the Osman Study provided that its “analysis was based on intent to *treat*”—*i.e.* it tested the drug, not cosmetic, effects of certain products. Osman Study at 1142 (RJN, Ex. E) (emphasis added). Notably, the Osman Study acknowledges that its results are inconclusive: “Further studies are needed to confirm our findings in other populations and to evaluate the effectiveness of other commonly used products in *preventing*” stretch marks. *Id.* at 1142(emphasis added). The Osman Study did not study whether the Palmer's Products reduce the appearance of stretch marks.

Next, Plaintiffs cite the Buchanan Study (*see* Compl. ¶ 6), which “determine[d] whether cocoa butter cream is *effective in preventing*” stretch marks in pregnant women. Buchanan Study at 65 (RJN, Ex. F) (emphases added). As in the Osman Study, the Buchanan Study studied whether cocoa butter was an “effective treatment” for stretch marks as compared to application of a placebo. *Id.* at 67; *see also* Ud-Din Article at 215 (RJN, Ex. D) (stating that the Buchanan Study analyzed the prophylactic treatment on the development of stretch marks

⁹ Only one of the studies, the Osman Study, purports to have tested a formulation provided by E.T. Browne, although it does not state whether it was any of the Products at issue in this case. *See Tubbs v. AdvoCare Int'l, LP*, No. CV 17-4454, 2017 WL 4022397, at *6 (C.D. Cal. Sept. 12, 2017) (“[S]tudies that did not involve the products at issue [are] insufficient” to demonstrate falsity).

between treatment and control groups). As with the Osman Study, the Buchanan Study did not study whether the Palmer's Products reduce the appearance of stretch marks.

Next, Plaintiffs rely on the Brennan Review, which by their own allegations concluded that “there was no statistically significant average difference in the *development* of stretch marks in women who received topical preparations with active ingredients” versus a placebo. Compl. ¶ 8 (emphasis added) (citing Brennan Review (RJN, Ex. G)). Plaintiffs’ reliance on the Hague Review fares no better as it “evaluate[d] and summarize[d] the different *treatment methods* for [stretch marks].” Hague Review at 559 (RJN, Ex. H). The Hague Review discussed the Osman and Buchanan Studies, which, as explained above, did not study whether the Products reduced the appearance of stretch marks; rather, they studied whether cocoa butter, when compared to a placebo, prevented the development, or aided in the treatment, of stretch marks. *See id.* at 559, 564, 565, 568.e17 (citing the Osman and Buchanan Studies). The Hague Review acknowledged that its results are inconclusive and concluded that “[f]urther randomized, controlled trials are needed before definitive conclusions and recommendations can be made.” *Id.* at 559. Neither the Brennan Review nor the Hague Review analyzed whether the Palmer's Products reduce the appearance of stretch marks.

C. The Moore Article Cited by Plaintiffs Recognizes That Moisturizers Such as the Products “Can Improve the Appearance of Stretch Marks”

Finally, and critically, Plaintiffs rely on the Moore Article which concluded that “although many creams, lotions, and oils on the market claim to *prevent* stretch marks, no proof exists that these *treatments* work.” Compl. ¶ 9 (emphasized added) (citing Moore Article (RJN, Ex. I)). Plaintiffs tellingly ignore the paragraph that follows, which acknowledges that “[t]he American Academy of Dermatology Web site also says that a moisturizer can improve the

appearance of stretch marks and reduce itchiness . . .” Moore Article at 758 (RJN, Ex. I) (emphases added).

In *Alamilla v. Hain Celestial Grp., Inc.*, 30 F. Supp. 3d 943 (N.D. Cal. 2014), plaintiffs brought an action against manufacturers of juice products that were allegedly misleadingly labeled and advertised because they did not disclose that the manufacturer’s pressure treatment deprived the juice of its nutritional value. *Id.* at 943–44. Plaintiffs’ complaint incorporated by reference an article that contradicted the claim by concluding “that pressurization has little or no effects on nutritional and sensory quality aspects of foods.” *Id.* at 944 (citation omitted). The court held that because the articles that plaintiffs cited “contradict the allegation upon which [plaintiffs’] entire complaint hinges,” dismissal with prejudice was warranted. *Id.* Courts in this Circuit have similarly held they need not accept as true allegations contradicting documents that are referenced in the complaint. *See e.g., Sobek*, 2004 WL 2809989, at *2; *Kardovich*, 97 F. Supp. 3d at 140 (citation omitted) (“where a conclusory allegation in the complaint is contradicted by a document attached to the complaint, the document controls and the allegation is not accepted as true”).

Similar to *Alamilla*, the Moore Article contradicts the very allegation upon which the entire Complaint relies—namely, that the Products’ representations are false, misleading, or deceptive. The Moore Article recognizes the difference between the *prevention* and *treatment* of stretch marks and the Products’ claim of affecting the *appearance* of stretch marks through moisturizing, which as discussed above, the FDA has recognized as a cosmetic claim. Because the Court need not accept as true allegations contradicting documents that Plaintiffs refer to in their Complaint, Plaintiffs’ claims should be dismissed on this ground alone. *See e.g., Alamilla*, 30 F. Supp. 3d at 944.

The Complaint fails to sufficiently allege that the Products' representations are false, deceptive, or misleading. Plaintiffs' allegations are thus insufficient to support claims that E.T. Browne engaged in false and misleading conduct in violation of the New York consumer protection statutes, breached any express warranty, or should be held liable for fraud. *See e.g.*, *Tomasino*, 44 F. Supp. 3d at 263 (dismissing §§ 349 and 350 claims and breach of express warranty claim based on the same conduct as the consumer protection claims); *Bowring*, 234 F. Supp. 3d at 392 (dismissing fraud claim based on the same conduct as §§ 349 and 350 claims). The Court should accordingly dismiss the Complaint.

III. THE COURT SHOULD DISMISS PLAINTIFFS' UNJUST ENRICHMENT CLAIM BECAUSE IT IS DUPLICATIVE OF PLAINTIFFS' OTHER CLAIMS AND BECAUSE PLAINTIFFS HAVE FAILED TO ALLEGE THAT THEY LACK AN ADEQUATE REMEDY AT LAW

Under New York law, “unjust enrichment is not a catchall cause of action to be used when others fail. It is available only in unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an *equitable obligation* running from the defendant to the plaintiff.” *Corsello v. Verizon New York, Inc.*, 18 N.Y.3d 777, 790 (2012) (emphases added). Such a claim “is not available where it *simply duplicates, or replaces*, a conventional contract or tort claim.” *Id.* (emphases added). Case law in the Second Circuit demonstrates that Plaintiffs' claim, which is based on the same allegations as their other claims, should be dismissed. *See e.g.*, *Sabatano v. Iovate Health Scis. U.S.A. Inc.*, No. 19 CV 8924, 2020 WL 3415252, at *8 (S.D.N.Y. June 22, 2020) (dismissing “unjust enrichment claim [as] duplicative of plaintiffs' other claims”); *Melendez v. ONE Brands, LLC*, No. 18 CV 06650, 2020 WL 1283793, at *8 (E.D.N.Y. Mar. 16, 2020) (“Because [plaintiff's] unjust enrichment claim is based on the same allegations as his other claims, and because [plaintiff] has not shown how it differs from these other claims, his unjust enrichment claim is

duplicative and must therefore be dismissed.”).

Moreover, unjust enrichment is an equitable remedy, which fails when a plaintiff has an adequate remedy at law. *See Samiento v. World Yacht Inc.*, 10 N.Y.3d 70, 81 (2008) (“unjust enrichment . . . does not lie as plaintiffs have an adequate remedy at law”). The Complaint does not allege that Plaintiffs lack an adequate legal remedy. Indeed, it alleges the opposite by purporting to plead claims *at law* for violation of the New York consumer protection statutes, breach of warranty, and fraud. And, although Plaintiffs plead those claims at law, they, along with Plaintiffs’ unjust enrichment claim, are unable to withstand this motion to dismiss. *See e.g.*, *Melendez*, 2020 WL 1283793, at *8, 10 (dismissing claims for violation of New York GBL §§ 349 and 350, breach of express and implied warranties, and unjust enrichment where “it [is not] clear why ‘equity and good conscience’ would require restitution”). For this additional reason, the Court should dismiss Plaintiffs’ claim for unjust enrichment.

CONCLUSION

For the foregoing reasons, Defendant E.T. Browne respectfully requests that the Court grant this Motion and dismiss the Complaint in its entirety, with prejudice.

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